UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

JANINE ALI Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01614-AJT-JFA

DECLARATION OF JEFFREY T. BOZMAN IN SUPPORT OF MOTION FOR ORDER TO ALLOW THE NOTICING PARTY TO FIRST QUESTION A DEPONENT

1. I, Jeffrey Bozman, declare as follows pursuant to 28 U.S.C. § 1746:

I am an attorney at the law firm of Covington & Burling LLP, counsel for Defendant Eli Lilly and Company ("Lilly"). I am a member in good standing of the bars of the Eastern District of Virginia, the Commonwealth of Virginia, and the District of Columbia. I have personal knowledge of the facts set forth in this Declaration, which I make to place before the Court documents and information relevant to its determination of Lilly's Motion for Judgment on the Pleadings.

2. Attached as Exhibit A hereto is a true and correct copy of Joint Stipulation on Proposed Prozac (Fluoxetine) Discovery, ECF No. 71 in *Hexum v. Eli Lilly and Co.*, No. 2:13-cv-02701-SVW-MAN, ECF No. 71 at 9 (C.D. Cal. Aug. 12, 2014).

3. Attached as Exhibit B hereto is a true and correct copy of Civil Minutes of Telephonic Status Conference, ECF No. 81 in *Hexum v. Eli Lilly and Co.*, No. 2:13-cv-02701-SVW-MAN, ECF No. 71 at 9 (C.D. Cal. Aug. 21, 2014).

4. Attached as Exhibit C hereto is a true and correct copy of a February 23, 2015 email from Brett Reynolds to counsel for Plaintiffs in this action, with deposition notices attached.

5. Attached as Exhibit D hereto is a true and correct copy of an April 8, 2015 email from R. Brent Wisner to Brian Stekloff.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on April 10, 2015 in Washington, D.C.

/s/ Jeffrey T. Bozman
Jeffrey T. Bozman (VSB 83679)

Exhibit A

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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SIDNEY CARTER,

Plaintiff,

v.

ELI LILLY AND COMPANY, a corporation; and DOES 1 through 50, inclusive,

Defendants.

ERIN HEXUM and NICK HEXUM,

Plaintiffs,

v.

ELI LILLY AND COMPANY, a corporation; and DOES 1 through 50, inclusive,

Defendants.

Case No.: CV 13-2700 GHK (FFMx)
Case No.: CV 13-2701 GHK (FFMx)
Case No.: CV 13-2702 GHK (FFMx)

DISCOVERY MATTER

JOINT STIPULATION ON PROPOSED PROZAC (FLUOXETINE) DISCOVERY

HEARING:
Date: September 2, 2014
Time: 10:00 AM
Place: Courtroom E - 9th Floor
Judge: Hon. Frederick F. Mumm

Discovery Cutoff: December 13, 2014

CLAUDIA HERRERA and PETER LOWRY,

Plaintiffs,

v.

ELI LILLY AND COMPANY, a corporation; and DOES 1 through 50, inclusive,

Defendants.

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Pursuant to Local Civil Rule 37-2.1, Defendant Eli Lilly & Company ("Lilly") and Plaintiffs Sidney Carter (Case No. CV 13-2700), Erin Hexum & Nick Hexum (Case No. CV 13-2701), and Claudia Herrera & Peter Lowry (Case No. CV 13-2702) (collectively, "plaintiffs") hereby submit this Joint Stipulation.

I. LILLY'S INTRODUCTORY STATEMENT

A. Plaintiffs' Proposed Discovery on Non-Cymbalta Products

This litigation presents a single, narrowly-focused issue: whether plaintiffs suffered adverse events due to discontinuing treatment with Cymbalta, a medicine approved for the treatment of certain mood and pain disorders. To recover on their claims, plaintiffs must prove that a deficiency in the warning on discontinuation symptoms contained in the FDA-approved Package Insert for Cymbalta led to their alleged injuries. Since Cymbalta's launch, that Package Insert has included a detailed three-paragraph warning on antidepressant discontinuation symptoms, reflecting the widespread clinical understanding that such symptoms "are common following antidepressant therapy."[1]

To date, Lilly has provided extensive discovery on the core merits issues raised by plaintiffs' claims. Lilly has produced 1.8 million pages of documents responsive to plaintiffs' requests for document discovery, including materials from the Investigational New Drug Application and New Drug Application files for Cymbalta.[2] (Decl. of Phyllis A. Jones ("Jones Decl."), ¶¶ 5-8.) Lilly has also

[1] David G. Perahia et al., *Symptoms following abrupt discontinuation of duloxetine treatment in patients with major depressive disorder*, 89 J. of Affective Disorders 207 (2005) (Jones Decl., Ex. A.)

[2] Plaintiffs' claim that "Lilly has not produced documents" in response to "a great many" document requests, (Jt. Stip., n. 4), is false. In accordance with a schedule agreed upon by the parties, Lilly served written responses and objections to Plaintiffs' document requests on December 16, 2013, and March 4, 2014. (Jones Decl., ¶¶ 3-4.) Lilly has made a production consistent with those responses and objections. (Jones Decl., ¶¶ 5-8.) To date, Plaintiffs have neither inquired about those responses or objections nor sought to meet and confer. In any event, the Cymbalta IND/NDA files are plainly responsive to many of Plaintiffs' document

produced three 30(b)(6) witnesses on Drug Safety Surveillance, Regulatory Affairs, and Sales Training issues relevant to Cymbalta. (Jones Decl., ¶ 10.)

Although it is uncontested that plaintiffs' claims relate to a single medicine — Cymbalta — and one, well-understood facet of its safety profile, plaintiffs have served broad discovery on Prozac (or fluoxetine, its generic compound), another Lilly product. It is undisputed that Prozac and Cymbalta are two separate medicines – unique chemical compounds with different mechanisms of action, separately approved by the FDA, and brought to market decades apart. More critically, plaintiffs' claims do not implicate Prozac. Plaintiffs do not allege that they took Prozac; nor do they claim that they suffered any injury as a result of Prozac use or discontinuation. Plaintiffs' pursuit of Prozac discovery, thus, far exceeds the boundaries of reasonable discovery allowed by the Federal Rules.

Moreover, responding to plaintiffs' proposed Prozac discovery threatens to impose a significant burden unjustified by any marginal potential relevance. It is a well-established rule that the scope of discovery may not be unhinged from its conceivable value to the merits of the case. *See Mailhoit v. Home Depot U.S.A., Inc.*, 285 F.R.D. 566, 571 (C.D. Cal. 2012). This analysis counsels against the Prozac discovery plaintiffs seek. Discovery on a decades-old product unrelated to plaintiffs' claims would impose a substantial burden on Lilly without advancing the understanding of the merits. This imposition is inappropriate here where the amount in controversy is minimal. Plaintiffs allege manageable symptoms for

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requests in these matters — a point that Plaintiffs cannot seriously contest. That Lilly produced those documents in a different matter is of no consequence because plaintiffs' counsel here are identical to those in that earlier matter, and Lilly has given the plaintiffs in this action full access to those documents. Finally, in response to Plaintiffs' request, Lilly has produced an index reflecting the Bates ranges for responsive documents contained in Lilly's productions to date. (Jones Decl. ¶ 9.)

which they pursued little or no treatment and, which, in some instances, lasted no more than several months.

Lilly accordingly seeks a protective order precluding any discovery on Prozac or fluoxetine, including the following discovery served by Plaintiffs to date (the "Proposed Prozac Discovery"):

- Requests for Production of Documents Nos. 125, 140, and 141 in the *Carter*, *Herrera*, and *Hexum* ("Prozac RFPs");
- the 30(b)(6) Notice on a 1997 Research Symposium on Discontinuation Syndrome served in *Carter* ("Research Symposium Notice"); and
- the Subpoena served on Maurizio Fava, M.D., and Jerrold F. Rosenbaum, M.D. ("Fava/Rosenbaum Subpoenas").

The parties have conferred on the Proposed Prozac Discovery, including during negotiations on the terms of the Stipulation Governing Protection of Confidential Information (Dkt. # 68).[3] They have been unable to agree.

B. Plaintiffs' Request to Quash Lilly's Properly Served Notices

As set out at IV.B, Lilly separately opposes Plaintiffs' request to quash the deposition notices served by Lilly on plaintiffs' prescribing physicians and to begin questioning in those depositions. Those notices were properly served by Lilly to comply with the Court's Scheduling Order on expert disclosures. Moreover, plaintiffs have exceeded the number of depositions to which they are entitled in the *Carter* and *Herrera* matters, rendering their notices invalid.

[3] The Stipulation Governing Protection of Confidential Information permits redaction of "those portions of documents that contain information relating to Defendant's products not at issue in this litigation." The Stipulation further permits a party to timely petition the Court for entry of an order altering or amending the terms of that provision.

II. PLAINTIFFS' INTRODUCTORY STATEMENT

There are unresolved discovery issues raised in Lilly's July 7, 2014 letter *and* in Plaintiffs' July 9, 2014 letter. *See* (Declaration of T. Matthew Leckman ("Leckman Decl."), Ex. A). Both letters were sent pursuant to Local Rule 37.

A. Lilly's Letter: "Prozac / Withdrawal Syndrome" Discovery

Lilly's own clinical data showed that 40-50% of Cymbalta users would suffer from withdrawal syndrome, and it was aware of that risk profile as early as 2005 and possibly sooner. *See* Jones Decl., Ex. A. Its product labeling has never disclosed that level of risk, instead misleadingly informing physicians and consumers – even to this very day – that the risk is simply "1% or greater."

Lilly has been marketing antidepressant medications – which now are well known to pose the risk of withdrawal syndrome, to varying degrees – since 1987, when Prozac was approved for sale in the United States. When competitor antidepressants first began to be introduced into the U.S. market (*e.g.*, GlaxoSmithKline's Paxil), Lilly made an affirmative marketing effort to attack those medications by pointing out they posed a higher risk / rate of withdrawal than Prozac. (Leckman Decl., Ex. B (Decl. of Joseph Glenmullen in *Saavedra v. Lilly*, 2:12-cv-09366-SVW-MAN (C.D. Cal)), at ¶¶ 27-29). Discovery on Prozac and withdrawal syndrome is relevant to Lilly's knowledge and culpability and to the question of punitive damages. And contrary to Lilly's suggestion, Plaintiffs are not seeking broad and expansive discovery of all things Prozac. Rather, all of Plaintiffs' Prozac-based requests, which are set forth below, seek production of Prozac materials *that involve* withdrawal symptoms. Discovery targeted to Prozac and withdrawal is probative of Lilly's early understanding of withdrawal syndrome, how the risk can vary significantly from one antidepressant to another, and the importance of conveying nuanced risk information to physicians and consumers.

Prozac / withdrawal discovery easily complies with the standard in Rule 26. A party may obtain discovery on "any nonprivileged matter that is relevant to any party's claim or defense" and "[r]elevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b). But, citing Rule 26(b)(2)(C), Lilly insists that the cost of this discovery is too high and the claimed damages are not worth the hassle. Neither argument has merit nor does it vitiate the clear relevance of this discovery to the claims at hand. Responding to Prozac / withdrawal discovery would not be any more cumbersome for Lilly – indeed, would not be any different *at all* – than any of the other discovery. And while it may be true that Lilly does not value the claims made in these cases, Plaintiffs have suffered greatly from Cymbalta and believe their damages have significant value. Indeed, if the amounts in controversy did not respectively exceed $75,000, the cases would lack diversity criteria in the first instance. Lilly has never claimed that to be the case, and that fact alone undercuts Lilly's "amount in controversy" argument. This Court should permit the discovery in question.

B. <u>Plaintiffs' Letter: Lilly's Refusal to Honor Plaintiffs' Subpoenas and Deposition Notices Directed to Their Prescribing Physicians</u>

On June 24, 2014, Plaintiffs sent out subpoenas for oral deposition (and accompanying deposition notices) to each of the physicians who prescribed Cymbalta for them. The subpoenas set the depositions for dates in October 2014. (Leckman Decl., Ex. C (Plaintiffs' Subpoenas and Deposition Notices to Prescribing Physicians). To date, no physician has indicated his or her inability to attend and testify pursuant to Plaintiffs' requests. To date, Lilly counsel has not advised that they are unable to attend any of the depositions as noticed by Plaintiffs.

But Lilly's counsel objected to Plaintiffs' subpoenas. And when the parties conferred, Lilly's counsel insisted the depositions must proceed before the expert disclosure deadline (September 22, 2014) and that no matter when the depositions proceed, Lilly's counsel – and not Plaintiffs' counsel – is entitled to question the physicians first in sequence. Undersigned Plaintiffs' counsel advised it was *possible* to conduct that depositions earlier, subject to the parties' availability and with two qualifiers: (1) Plaintiffs do not join in Lilly's position that this testimony (for instance, on the learned intermediary doctrine) has any bearing on expert reports, and thus, the depositions need not necessarily precede the expert deadlines; and (2) the depositions could proceed earlier *only if* Lilly agreed to honor Plaintiffs' original subpoenas and notices and allow Plaintiffs' counsel to question each witness first in sequence. Lilly refused. Instead, on July 21, 2014, Lilly simply issued its own subpoenas and notices for the very same physicians, setting their depositions for dates in August and September 2014. (Leckman Decl., Ex. D (Lilly's Counter-Subpoenas and -Deposition Notices).

This attempted tactic is not new to pharmaceutical cases. The testimony of a prescribing physician is central to proximate causation (*i.e.*, did the inadequate warning causally link to receipt of the drug and consequent injury) and attorneys perceive a tactical advantage in questioning the prescriber first. But there is absolutely no authority permitting a party to circumvent an opposing party's deposition notice, countering with its own notice and demanding to wrest control of the questioning sequence. (Leckman Decl., Ex. E (Order and Briefing in *Kammerer v. Wyeth*, 8:04-cv-00196-JFB –TDT, (D. Neb.)). This Court should reject the tactic and quash Lilly's counter-subpoenas and notices.[4]

[4] Another statement in Lilly's introductory remarks warrants a response, lest it go un-rebutted. Lilly claims it has produced 1.8 million documents so far in discovery. That may be true. But nearly all of those 1.8 million documents are contained in the New Drug Application (NDA), which Lilly produced to undersigned Plaintiffs' counsel in another Cymbalta withdrawal case, *Carnes v.*

III. LILLY'S DISPUTED ISSUES

As discussed below at III.D, the scope of inquiry reflected in plaintiffs' Proposed Prozac Discovery is overbroad and not reasonably calculated to lead to the identification of admissible evidence. Satisfying this discovery would impose an undue burden not justified by any marginal relevance.

A. 1st Disputed Issue: Prozac RFPs

The Prozac RFPs seek documents referring to potential antidepressant discontinuation-emergent adverse events, but purport to capture documents relating to "Prozac or fluoxetine," a medicine outside the scope of Plaintiffs' claims. Pursuant to LR-37-2.1, the Prozac RFPs are set out in full below.

REQUEST NO. 125[5]

Lilly, 0:13-cv-00591-CMC (D. S.C.), prior to discovery in these three cases. Lilly did so pursuant to Court order in that case. The **only** materials it has made in these cases are two much smaller sets of documents. And notwithstanding Plaintiffs' requests, upon the first exchange of this Joint Stipulation Lilly still had not specified which documents respond to which requests. It was not until August 6, 2014, after undersigned Plaintiffs' counsel drafted this footnote, that Lilly purported to index its production to date. Undersigned has not had a full opportunity to review that index and cannot take any position on whether it is sufficient or complete. Moreover, Plaintiffs first served Lilly with their 167 requests for production of documents and things on October 15, 2013, nearly ten months ago. Lilly has not produced documents in response to a great many of those requests. At bottom, Lilly has done as little as possible to produce relevant documents in these three cases, and its contention about the volume of production so far is belied by that reality. In the interest of time, the instant motion is addressed only to the two disputes set forth in text. However, pursuant to the parties initial meet-and-confer, they anticipate further use of the Local Rule 37 process to address these separate production issues. Plaintiffs highlight this issue here solely to give proper context to Lilly's introductory comments.

[5] Lilly objected as follows to Request No. 125:

RESPONSE TO REQUEST NO. 125

"Lilly incorporates its General Objections as if fully set forth herein. Lilly objects to this Request and its use of "ALL DOCUMENTS" and "withdrawal, discontinuation, dependence or addiction" as overly broad, unduly burdensome, and vague as to time, scope, and subject matter. Lilly objects further to this Request to the extent that it is not limited to documents relating to Plaintiff's treatment with Cymbalta or any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that

"All DOCUMENTS that refer to Prozac or fluoxetine and withdrawal, discontinuation, dependence or addiction."

REQUEST NO. 140[6]

"All articles authored, co-authored, ghost-written or sponsored by YOU which discuss withdrawal, discontinuation, dependence, addiction, whether related to Cymbalta or not, including but not limited to articles that reference Prozac/fluoxetine."

REQUEST NO. 141[7]

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is neither relevant nor likely to lead to the discovery of admissible evidence. The Complaint makes no allegations regarding discontinuation symptoms associated with Prozac and as such, documents relating to discontinuation symptoms associated with Prozac are irrelevant in this matter. Lilly objects additionally to this request to the extent that is seeks documents protected by the attorney-client privilege, work-product doctrine or other immunity."

[6] Lilly objected as follows to Request No. 140:

RESPONSE TO REQUEST NO. 140

"Lilly incorporates its General Objections as if fully set forth herein. Lilly objects to this Request and its use of "All articles" as overly broad, unduly burdensome, and vague as to time, scope, and subject matter. Lilly objects further to this Request to the extent that it is not limited to documents relating to Plaintiff's treatment with Cymbalta or any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Lilly objects additionally to this Request to the extent that it seeks documents protected by the attorney-client privilege, work-product doctrine, or other immunity. Moreover, Lilly objects to this Request to the extent that it seeks documents not in Lilly's possession, custody, or control."

[7] Lilly objected as follows to Request No. 141:

RESPONSE TO REQUEST NO. 141

"Lilly incorporates its General Objections as if fully set forth herein. Lilly objects to this Request and its use of "All CME presentations" as overly broad and unduly burdensome. Lilly objects further to this Request to the extent that it is not limited to documents relating to Plaintiff's treatment with Cymbalta or any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Lilly objects additionally to this Request to the extent that is seeks documents protected by the attorney-client privilege, work-product doctrine, or other immunity."

"All CME presentations sponsored by YOU which mention withdrawal, discontinuation, dependence or addiction, whether related to Cymbalta or not, including but not limited to presentations that reference Prozac/fluoxetine."

B. 2nd Disputed Issue: Research Symposium Notice

Citing a May 6, 2007 *New York Times Magazine* article entitled "Self-Nonmedication" by former Effexor patient Bruce Stutz, the Research Symposium Notice requests testimony about "[t]he 1997 Research Symposium conducted by Eli Lilly & Company relating to 'discontinuation syndrome[.]'" The Research Symposium Notice seeks testimony on six topics:

1. the identity of all Lilly employees, agents, or third parties retained by Lilly (*e.g.*, thought leaders) responsible for conceiving of and presenting the symposium, including collection of data, research, or literature leading up to the symposium and recruitment of speakers or participants in the symposium;
2. the identity and/or name of any committee or group convened at or retained by Lilly for the purpose of planning or publicizing the symposium;
3. the identity of all Lilly employees, agents, or third parties retained by Lilly (*e.g.*, thought leaders) responsive for the writing, drafting, creation, production, publication, dissemination, or distribution of any and all documents, materials, or other tangible items, including by not limited to audio or visual media or materials, used at or made available to any speakers, participants, or attendees of the symposium;
4. the identity of all Lilly employees, agents, or third parties retained by Lilly (*e.g.* thought leaders) responsible for training, educating,

or meeting with any speakers or participants in advance of the symposium;

5. the identity of all Lilly employees, agents, or third parties retained by Lilly (*e.g.*, thought leaders) who attended the symposium; and

6. the retention and location of any and all documents, materials and things that were produced by Lilly as a result of, or in response to, the symposium, including but not limited to any memorandum, minutes of meetings, correspondence between or among Lilly employees, and/or sales or marketing materials.

The Research Symposium Notice also includes two document requests:

1. Any and all documents, materials and things relating to the symposium, including but not limited to audio or video recordings of any part of the symposium.

2. Any and all documents, materials and things read, reviewed, or used by this corporate designee in order to prepare for his/her testimony on the topics set forth above."

C. <u>3rd Disputed Issue: The Fava/Rosenbaum Subpoenas</u>

The Fava/Rosenbaum Subpoenas seek documents from Maurizio Fava, M.D. and Jerrold F. Rosenbaum, M.D., both of Massachusetts General Hospital, on eight separate topics:

1. A copy of any paper, whether peer reviewed or not, which you authored, co-authored, drafted, edited, or revised, relating to antidepressant withdrawal or discontinuation syndrome (or symptoms);

2. Any document, research or data relied upon by you in authoring or co-authoring any paper relating to antidepressant withdrawal or discontinuation syndrome (or symptoms);

3. A copy of any paper, whether peer reviewed or not, which you authored, co-authored, drafted, edited, or revised and for which Eli Lilly & Company (hereinafter "Lilly") provided any support or funding;

4. Any document, and any draft thereof, constituting or reflecting an agreement or contract between you and Lilly relating to your study of withdrawal or discontinuation syndrome (or symptoms) in antidepressant users, including but not limited to the study reported in your article *Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial*, published in 1998 in the journal for the Society for Biological Psychiatry;

5. Any correspondence between you and Lilly relating to the study of withdrawal or discontinuation syndrome (or symptoms) in antidepressant users, including but not limited to the study reported in your article *Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial*, published in 1998 in the Journal for the Society for Biological Psychiatry;

6. Any document, in any form whatsoever, reflecting statements by Lilly, or any Lilly employee, agent, or contractor, in response to work-product created or generated by you, alone or together with any other person, relating to withdrawal or discontinuation syndrome (or symptoms) in antidepressant users, including but not limited to the study reported in your article *Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial*, published in 1998 in the [J]ournal for the Society for Biological Psychiatry; and

7. Any document, research, or data provided by Lilly to you, or by you to Lilly, relating to antidepressant withdrawal or discontinuation syndrome (or symptoms); and

8. Any document reflecting or memorializing payments to you from Lilly.

D. Lilly's Position on Its 1st, 2nd, and 3rd Disputed Issues

Plaintiffs' Proposed Prozac Discovery violates the well-established mandate that discovery must be "relevant to any party's claim or defense" or "reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). *See In re ATM Fee Antitrust Litigation*, No. C 04-02676 CRB, 2007 U.S. Dist. LEXIS 47943, at *14 (N.D. Cal. June 25, 2007) ("[D]iscovery is limited to the specific subject matter presented by Plaintiff's complaint.") The requested discovery fails on both counts: plaintiffs' claims do not implicate Prozac or fluoxetine; nor is discovery on this distinct compound likely to yield evidence bearing on the issues relevant to this suit. Even if the Proposed Prozac Discovery offered some marginal relevance to the claims in this litigation, it is not proportional to the needs of the case. The burden and expense arising from the collection, review, and production of documents related to Prozac would quickly overtake any probative value arising from this discovery or the recoverable damages.

1. **The Proposed Prozac Discovery Is Not Relevant.**

Prozac's life cycle significantly pre-dates Cymbalta's approval and plaintiffs' treatment with Cymbalta. The FDA first approved Prozac for the treatment of depression in 1987, seventeen years before Cymbalta's initial approval in 2004. That temporal relationship is further attenuated for these

plaintiffs: the first of the plaintiffs to take Cymbalta (Ms. Herrera) allegedly began treatment in 2006, nearly two decades after Prozac's approval. Nor are Cymbalta and Prozac identical medicines, as Plaintiffs' sweeping inclusion of Prozac matters in this litigation would suggest. Prozac is a selective serotonin reuptake inhibitor, or SSRI, whose mechanism of action includes preventing the reuptake of the neurotranmitter serotonin. Cymbalta, by contrast, is a serotonin and norepinephrine reuptake inhibitor, or SNRI, which affects the reuptake of two neurotransmitters, serotonin and norepinephrine. These foundational differences between the two medicines are indisputable.

Given these plain distinctions, plaintiffs can point to no justification for wide-ranging discovery on Prozac, a product with no relevance to the core merits questions presented. None of the plaintiffs here have alleged injury arising from the use, or discontinuation, of Prozac. Nor do they claim damages resulting from Lilly's conduct with respect to the development, approval, or marketing of Prozac.

Lastly, the Proposed Prozac Discovery can have no material bearing on establishing Lilly's notice of the risk of discontinuation events. The Cymbalta clinical trial program was constructed to evaluate the frequency of discontinuation-emergent adverse events, and the Cymbalta Physician Package Insert has warned of the possibility of discontinuation symptoms since the product's launch. (Jones Decl., Ex. B, at 6.) Indeed, the article on which plaintiffs' claims are premised reflects Lilly's close attentiveness to the occurrence of discontinuation-emergent adverse events in patients ceasing Cymbalta therapy. David G. Perahia et al., *Symptoms following abrupt discontinuation of duloxetine treatment in patients with major depressive disorder*, 89 J. of Affective Disorders 207 (2005) (Jones Decl., Ex. A.) In short, Lilly has acknowledged, studied, and warned of potential Cymbalta discontinuation symptoms since the product's development. The expansive discovery sought by the Prozac RFPs on

discontinuation symptoms allegedly related to a separate, non-Cymbalta medicine will do nothing to illuminate this core point further.

The Research Symposium Notice and the Fava/Rosenbaum Subpoenas likewise exceed the scope of permissible discovery. The Research Symposium Notice references a narrative essay published in the *New York Times Magazine* and a 1997 symposium on antidepressant discontinuation. (Jones Decl., Ex. C.) Cymbalta was featured in neither. Indeed, the author of the essay was treated with Effexor, not Cymbalta, and the symposium predated Cymbalta's approval by seven years.

The Fava/Rosenbaum Subpoenas are similarly improper to the extent that they seek any documents relating to the article entitled *Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome* published in 1998 in the Journal for the Society for Biological Psychiatry. On its face, that article — published six years before Cymbalta's approval — addresses symptoms arising from the discontinuation of SSRIs, a therapeutic class unrelated to plaintiffs' claims. Plaintiffs should not be permitted to use the third-party discovery procedures afforded under Fed. R. Civ. P. 45 as a mechanism for securing discovery to which they would not otherwise be entitled.

2. <u>The Proposed Prozac Discovery Is Unduly Burdensome.</u>

Lilly maintains that the Proposed Prozac Discovery is not relevant. However, even if the Proposed Prozac Discovery offered the remote possibility of yielding some marginally relevant evidence, it is inconsistent with the proportionality dictates of the Federal Rules to burden Lilly with locating, reviewing, and producing decades of accumulated Prozac information. As this Court has held, it is appropriate to limit discovery when "the burden or expense of the proposed discovery outweighs its likely benefit." *Mailhoit*, 285 F.R.D. at 571. *See also Barcenas v. Ford Motor Co.*, No. C 03-04644 RMW (EAI), 2004 U.S.

Dist. LEXIS 25279, *5 (N.D. Cal. Dec. 9, 2004) (the court has discretion to limit discovery if the burden or expense of the proposed discovery outweighs its likely benefit); *Piacenti v. GMC*, 173 F.R.D. 221, 224 (N.D. Ill., April 22, 1997) ("The legal tenet that relevancy in the discovery context is broader than in the context of admissibility should not be misapplied so as to allow fishing expeditions in discovery."). This foundational principle is reflected in the pending amendments to Fed. R. Civ. P. 26(b)(1), which advise that discovery must be "proportional to the needs of the case." [8] That proportionality calculus accounts for "the amount in controversy," the "importance of the discovery in resolving the issues," and (3) "whether the burden or expense of the proposed discovery outweighs its likely benefit." [9]

Courts have applied this proportionality principle to bar discovery on products beyond those specifically at issue in litigation. Indeed, this Court has held that discovery "must be limited to the 'Accused Products'" or else risk being unduly burdensome. *Superior Commc'ns v. Earhugger, Inc.*, 257 F.R.D. 215, 220 (C.D. Cal. 2009). Even when products fall into the same general category – for example, "tires" or "drugs" – it is common practice to deny discovery on products that are not the subject of the litigation. For example, in *Depomed, Inc. v. Lupin Pharms. Inc.*, No. C 09-05587 LB, 2012 U.S. Dist. LEXIS 6799 (N.D. Cal. January 20, 2012), the Court denied discovery on drugs other than "the two products at issue" to prevent plaintiff from "min[ing]without restriction,

[8] *See* Preliminary Draft of Proposed Amendments to the Federal Rules of Bankruptcy and Civil Procedure, August 2013.

[9] Factors to consider when assessing proportionality include (1) the amount in controversy, (2) the importance of the issues at stake in the action, (3) the parties' resources, (4) the importance of the discovery in resolving the issues, and (5) whether the burden or expense of the proposed discovery outweighs its likely benefit. *See* Preliminary Draft of Proposed Amendments to the Federal Rules of Bankruptcy and Civil Procedure, August 2013.

[defendant's] institutional knowledge" of certain drug delivery systems. *See also Barcenas* 2004 U.S. Dist. LEXIS 25279 (denying discovery related to one tire model in a case involving a different tire model); *Piacenti*, 173 F.R.D. at 225 (denying discovery of a vehicle model similar to the one at issue in the suit, because "plaintiff's discovery request does not appear to be reasonably calculated to lead to the discovery of admissible evidence."). To allow discovery on products not at issue in the suit risks making discovery overbroad and unnecessarily burdensome. *In re ATM Fee Antitrust Litig.*, 2007 U.S. Dist. LEXIS 47943, at *14 (holding that "production of information about ATM networks other than Star is unnecessarily burdensome" and limiting discovery); *see also Bryant v. Mattel, Inc.*, Nos. C04-09049 SGL (RNBx), CV04-09059, CV05-2727, 2007 WL 5432959, at *4 (C.D. Cal. Apr. 19, 2007) (plaintiff's requests were "clearly overbroad, extending far beyond the single [advertisement] that MGA has contended is actionable").

Plaintiffs' Proposed Prozac Discovery violates the bedrock principle that a court must not allow the burden associated with discovery to outstrip its potential relevance. Here, Plaintiffs' Prozac RFPs seek the identification, collection, review, and production of documents relating to a decades-old compound that is not at issue in this litigation. Even if this resource-intensive enterprise yielded documents of some limited relevance, that could not justify the significant burden imposed.

So, too, with the Research Symposium Notice. That Notice seeks a witness prepared to testify in detail concerning the planning, execution, and aftermath of a meeting that occurred nearly twenty years ago. Providing this testimony, in conjunction with the documents called for by the Notice, would require a significant collection and review exercise — all to pursue information about a meeting focused on a drug the plaintiffs never took. This diversion of case

resources is particularly inappropriate in the service of a question that is settled: Lilly has long acknowledged the potential risk of Cymbalta discontinuation symptoms and warned of that risk since the medicine's launch.

Nor is this burden justified by the damages alleged, or recoverable, here. To date, three plaintiffs – Mr. Carter, Ms. Herrera, and Ms. Hexum – have been deposed. They allege symptoms for which they received minimal or limited medical treatment. (Jones Decl., Exs. D, E, K.) Ms. Hexum, for her part, conceded that her "major symptoms" resolved "within a month" and that she fully recovered just a few months later. (Jones Decl., Ex. D.)

Given the irrelevance of the matters sought in the Proposed Prozac Discovery and the significant burden attendant to satisfying that discovery, "[t]he potential for turning up a needle does not require Defendants to sift through this haystack." *In re ATM Fee Antitrust Litigation*, 2007 U.S. Dist. LEXIS 47943, at *20. Lilly's motion for protective order should accordingly be granted.

E. Plaintiff's Response to Lilly's Disputed Issues

Again, Lilly is wrong in its insistence that Prozac / withdrawal discovery is improper.

First, Lilly simply lacks standing to quash the third-party subpoenas directed at Drs. Fava and Rosenbaum. *See California Sportfishing Protection Alliance v. Chico Scrap Metal, Inc.*, 2014 WL 641139, at *5 (E.D. Cal. Feb. 18, 2014) ("The general rule … is that a party has no standing to quash a subpoena served upon a third party, except as to claims of privilege relating to the documents being sought.") Lilly makes no privilege claims here, and accordingly, its request for a protective order on that particular production fails outright.

Second, Lilly ignores the plain definition of "relevance" in Rule 26(b). Instead, Lilly leans on a "proportionality" position deriving from case law that does not support its argument. For instance, Lilly's heavy reliance on *ATM Fee*

Antitrust Litigation, 2007 WL 1827635, at *5 (N.D. Cal. June 25, 2007), is misguided. There, the court denied the plaintiffs' requested discovery on several grounds, not the least of which was the fact that the plaintiffs had previously stipulated not to seek some of the materials in question. *Id.* at *4. The parties here have never had any such agreement. Additionally, the *ATM Fee* court likened the plaintiffs' "unreasonably broad" and "purely speculative" requests to a demand that the defendants search a haystack for a needle. *Id.* at *3, 5. There is no such "needle in the haystack" danger here, where Plaintiffs have not asked for *all* Prozac documents, but rather, for those that deal with the very set of injuries at issue in this case, *i.e.*, withdrawal injuries. There cannot be a serious contention on Lilly's part that this request is an unreasonably broad one. As explained above, it is certainly not a speculative one. Nor is there any similarity between Plaintiffs' instant targeted requests and the unrestricted "mining" of a company's "institutional knowledge" that the court refused to condone in *Depomed, Inc. v. Lupin Pharms. Inc.*, No. C 09-05587 LB, 2012 U.S. Dist. LEXIS 6799 (N.D. Cal. May 17, 2011).

In short, Prozac / withdrawal discovery asks for production of materials that undeniably exist and undeniably will shed light on the nature and extent of Lilly's failure to properly warn the medical community concerning the withdrawal risk profile of Cymbalta. Lilly's request for a protective order should be rejected and the discovery permitted.

IV. PLAINTIFFS' DISPUTED ISSUES

A. Plaintiffs' Position on Their Disputed Issues

As set forth above, Plaintiffs dispute Lilly's attempt to circumvent Plaintiffs' duly served subpoenas and deposition notices for their prescribing physicians and Lilly's claim that it is entitled to question them first in sequence.

No further citation is needed here because there is no basis in procedural or substantive law for such a maneuver. Plaintiffs urge the Court to quash Lilly's subpoenas and notices of deposition. Plaintiffs further urge the Court to enter an order directing that Plaintiffs' counsel will proceed first in sequence in questioning each of the physicians at issue.

B. Lilly's Response to Plaintiffs' Disputed Issues

In its October 21, 2013 Scheduling Order, the Court made clear that the "parties shall designate their expert witnesses, and make the required disclosures, by no later than September 22, 2014." (Dkt. # 37.) It was likewise clear that it intends to adhere closely to the discovery schedule set in these matters. (*Id.* ("Inasmuch as we have set this lengthy discovery period based on counsel's request, the discovery completion date will NOT be extended.").) The logical consequence of the Court's direction is that fact discovery intended to be relied upon by any expert should be completed by no later than September 22, 2014. In a products liability failure-to-warn suit, this would necessarily include the deposition testimony of any medical professional who prescribed Cymbalta to plaintiffs or treated their alleged injuries.[10] To ensure the development of the necessary factual record in advance of expert disclosures, Lilly asked that the parties endeavor to schedule depositions in advance of the Court's September 22 deadline. (Jones Decl., Ex. F.) In response to Lilly's request, plaintiffs conditioned agreement on Lilly's concession that plaintiffs' counsel would be permitted to examine the relevant doctors first and refused to engage in further

[10] Despite Plaintiffs' insistence that the testimony of prescribing and treating physicians have no bearing on the issues in this suit, it is routinely the case that medical experts in product liability suits raising questions about prescribing decisionmaking and causation to opine on the testimony of a plaintiff's prescribing and treating physicians. Even if plaintiffs do not intend to have their experts rely on the testimony of plaintiffs' prescribing physicians, Lilly is not prepared to waive that opportunity.

scheduling discussions absent that concession. (*Id.*) To ensure the ability to schedule these depositions in sufficient time to satisfy the Court's expert disclosure deadline, Lilly noticed and served the depositions for dates in advance of the September 22 deadline, (Jones Decl., Ex. G), and intends to lead the questioning in these depositions.

Plaintiffs' dogged insistence that they be permitted to commence questioning in these depositions is meritless. They cite no authority in support of their position — not because it is self-evident, but because there is none. Indeed, the single order they attach in support of their view arises from a factual situation so far removed from the issue before the Court that it is of no use.

In addition, Mr. Carter and Ms. Hexum have noticed depositions beyond the number permitted under the Federal Rules, rendering plaintiffs' physician notices in those matters invalid. Rule 30 permits a party 10 depositions each, absent an order of the Court. Fed. R. Civ. P. 30(a)(2)(A)(i). To date, Plaintiffs have noticed 46 depositions across the *Carter*, *Herrera*, and *Hexum* matters, including 23 in *Carter* and 14 in *Hexum*.[11] Lilly has not agreed to allow plaintiffs to take depositions above the limit permitted by the Federal Rules, and plaintiffs were not entitled to serve further notices as of June 24, the date on which they noticed the physician depositions at issue.

In sum, Lilly should be permitted to proceed with its properly-noticed physician depositions, and, as the noticing party, should be permitted to question deponents first.

[11] In *Carter*, plaintiff served four 30(b)(6) notices, seventeen sales representative notices, and two physician notices. (Jones Decl., Exs. H, I, J.) In *Hexum*, plaintiff served three 30(b)(6) notices, nine sales representative notices, and two physician notices. (*Id.*) Although Plaintiffs have indicated their intention to limit the number of sales representative depositions taken in these cases, they have not provided Lilly with any information on what sales representative depositions they will forgo.

DATED: August 12, 2014

/s/ T. Matthew Leckman

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DATED: August 12, 2014

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Attorneys for Eli Lilly & Company

ATTESTATION:

I hereby attest that T. Matthew Leckman has concurred in this filing's content and has authorized this filing.

/s/ Phyllis A. Jones
Attorney for Eli Lilly & Company

Exhibit B

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	CV 13-2700 GHK (FFMx) CV13-2701 GHK (FFMx) CV13-2702 GHK (FFMx)	Date	August 21, 2014
Title	SIDNEY CARTER v. ELI LILLY AND COMPANY, et al. ERIN HEXUM, et al. v. ELI LILLY AND COMPANY, et al. CLAUDIA HERRERA, et al. v. ELI LILLY AND COMPANY, et al.		

Present: The Honorable	Frederick F. Mumm, United States Magistrate Judge	
James Munoz	N/A	None
Deputy Clerk	Court Reporter / Recorder	Tape No.
Attorneys Present for Plaintiff:	Attorneys Present for Defendant:	
Kevin O'Brien	Phyllis Jones	

Proceedings: **(IN CHAMBERS) TELEPHONIC STATUS CONFERENCE**

Telephonic status conference held regarding discovery dispute. Parties make their appearance.

Court finds that plaintiffs are entitled to priority in questioning certain witnesses.

: 05

Initials of Preparer JM

Exhibit C

From:	Reynolds, Brett
To:	bhunt@millerlegalllc.com; rbwisner@baumhedlundlaw.com; "pmiller@millerlegalllc.com"
Cc:	Imbroscio, Michael; Jones, Phyllis; Bozman, Jeffrey
Subject:	CYMBALTA DEAE DISCOVERY - Ali and Hagan-Brown Deposition Notices
Date:	Monday, February 23, 2015 4:27:00 PM
Attachments:	Ali -Patla.pdf Hagan Brown-Bahadori.pdf Ali -Ahmad.pdf Ali- Allah.pdf image001.png

Counsel,

Please see the attached deposition notices in the *Ali* and *Hagan-Brown v. Eli Lilly and Co.* matters.

Brett

Brett Reynolds

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Exhibit D

From: Wisner, R. Brent
To: Stekloff, Brian; Imbroscio, Michael; Reynolds, Brett; Holmes, Jennifer
Cc: Jison, Samantha; Baum, Michael; pmiller@millerlegalllc.com
Subject: RE: Doctor Deposition Update
Date: Wednesday, April 08, 2015 6:18:30 PM
Attachments: image005.png
Hagan- Depo Notice Dr Bahadori.pdf
Hagan-Brown- Intent to Serve Depo Dr Bahadori.pdf

Brian,

Thanks for the quick response. I plan to ask Dr. Bahadori questions first at the deposition and if you want to go to the Court about this, I am fully prepared to argue this issue. As you can see from the attached, Dr. Bahadori will make himself available on April 17, 2015. This would, however, be the date on which a motion would be heard on this issue. Thus, if Lilly wants to raise this issue with the Court, I would be amenable to requesting a hearing on the Thursday, April 17, 2015 *before* the deposition. Indeed, there appears to be other discovery issues that will need to be presented to the Court, and it might be best to having a hearing on all of them a day earlier. If Lilly is amenable to this, please let me know, and I will reach out to the Court tomorrow morning.

I am going to try and explain why the Plaintiff has the right to ask questions first. In an email dated February 18, 2015 at 7:26 PM—before any deposition notice in this case—I notified Lilly that Plaintiffs would be asking questions first during the doctor depositions and that any deposition notice without any context or conference with counsel would be disregarded. The law is clear—deposition notices do not dictate who gets to ask questions first. *See United States v. Bartesch*, 110 F.R.D. 128, 129 (N.D. Ill. 1986) ("[I]t is clear that the priority rule, which confers priority on the party who first serves notice of taking a deposition, is abolished by Rule 26(d)."). It would be silly for the order of questioning to be dictated by whomever emails a pointless piece of paper first. The rules abandoned that approach. Notwithstanding, Brett felt compelled to disregard this email and serve a deposition notice on February 23, 2015. That notice has *no* bearing on who gets to ask questions first—especially since Lilly was on notice of Plaintiff's position to ask questions first before the deposition notice was issued. *See Occidental Chem. Corp. v. OHM Remediation Servs.*, 168 F.R.D. 13, 14 (W.D.N.Y. 1996). And to be clear, Plaintiff has not had any discussions with Dr. Bahadori about his treatment of Plaintiff so this is not a situation like *Lumpkin v. Kononov*, No. 2:12-CV-320, 2013 WL 1343666, at *1 (N.D. Ind. Apr. 3, 2013) where Plaintiff already knows Dr. Bahadori's testimony.

Legally and practically, Plaintiff should be allowed to ask questions first. After all, Plaintiff has the burden to establish causation in this case and, thus, should be allowed to take the first shot at meeting that burden during the deposition. I explained this in a email over a month ago:

> Plaintiffs believe they are entitled to ask questions first and get the physician's state of knowledge on the record. For the purposes of this issue, we want to focus on the prescribing physician. Lilly argues in each case that each physician has "independent knowledge" of the risks of withdrawal, arguing that physicians have divined the true risks of withdrawal from common knowledge, their practice, and the U.S. label's "greater than or equal to 1%" language. Plaintiffs have a right to explore that issue before Lilly poisons the well by feeding the true risks to the physician and getting them to say "yeah, I guess I knew that…" This issue has been dispositive in two previous cases (*Carnes* and *McDowell*) and, since Plaintiff bears the burden of proof, Plaintiff should have the right to explore this area on the record *before* Lilly mounts its causation challenge. Fairness, justice, and commonsense dictate as much.

Email sent Feb. 24, 2015. Plaintiffs have the obligation to prove causation and thus have the right to present evidence first to meet that burden as in any court proceeding, e.g., a deposition.

Attached you will find a deposition notice and a notice of an intent to serve a subpoena. I've already confirmed the date with Dr. Bahadori, so I plan to ask my hour of questions of him first starting at 9:00 a.m. on April 17, 2015 pursuant to a valid deposition notice and valid subpoena.

Brent

From: Stekloff, Brian [mailto:BStekloff@cov.com]
Sent: Wednesday, April 08, 2015 1:18 PM
To: Wisner, R. Brent; Imbroscio, Michael; Reynolds, Brett; Holmes, Jennifer
Cc: Jison, Samantha; Baum, Michael; pmiller@millerlegalllc.com
Subject: RE: Doctor Deposition Update

Brent:

We are available on the mornings of April 17 and 24 for a deposition of Dr. Bahadori. We prefer

April 17. We agree to the cost split proposed below as well.

As you know from Brett's email dated February 23, 2015 at 4:28PM ET, we have noticed the deposition of Dr. Bahadori and we intend to question Dr. Bahadori first during the first two hours of the three-hour window.

We will let you know by Friday COB if we intend to depose any of Mrs. Hagan-Brown's other physicians.

Please let us know when you finalize the date with Dr. Bahadori and whether he prefers for the deposition to take place at his office or at an alternative location.

Brian

Brian Stekloff

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From: Wisner, R. Brent [mailto:rbwisner@baumhedlundlaw.com]
Sent: Wednesday, April 08, 2015 3:49 PM
To: Wisner, R. Brent; Imbroscio, Michael; Stekloff, Brian; Reynolds, Brett; Holmes, Jennifer
Cc: Jison, Samantha; Baum, Michael; pmiller@millerlegalllc.com
Subject: RE: Doctor Deposition Update

Counsel,

Dr. Mohamed Bahadori is available for a deposition. He wants to limit the deposition to three hours. He also will charge $1,000 per hour of deposition and expects to be paid up-front with a cashier's check. I propose that we agree to split the cost of the deposition according to the time used. I plan to ask questions for one hour, i.e., $1,000. That leaves Lilly with the remaining two hours (or less, as Lilly chooses), i.e., $2,000. Would Lilly agree to such a cost split? Please let me know if this works for you.

Also, Dr. Bahadori would like to have this deposition done on a Friday in the morning. Please advise whether April 17 or 24 would be a problem for Lilly. I will of course coordinate with Dr. Bahadori.

Finally, please let me know if Lilly would also like to depose any of Plaintiff Gilda Hagan-Brown's other physicians as soon as possible.

Thanks,

Brent

From: Wisner, R. Brent
Sent: Monday, April 06, 2015 9:06 PM
To: Imbroscio, Michael; 'Stekloff, Brian'; Reynolds, Brett; 'Holmes, Jennifer'
Subject: Doctor Deposition Update

Counsel,

I have gotten a hold of each doctor and they have agreed to set aside a date in the next 2 – 3 weeks for their depositions. I should get hard dates in the next few days. Once I do, I will let you know.

Best,

R. Brent Wisner, Esq.
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related penalties under the Internal Revenue Code.